K040174

MAY 1 4 2004

510(k) Summary

Introduction

According to the requirements of 21 CFR 807.92, the following information provides sufficient detail to understand the basis for a determination of substantial equivalence.

1) Submitter name, address, contact

Roche Diagnostics Corporation
9115 Hague Rd.
Indianapolis, IN 46250

Contact Person: Jennifer Tribbett

Date Prepared: January 23, 2004

2) Device name

Proprietary name: Bilirubin Assay on the OMNI S Analyzer

Common name: Bilirubin (total and unbound) in the neonate test system

Classification name: Bilirubin (total and unbound) in the neonate test system

3) Predicate device

The bilirubin parameter for use on the OMNI S Analyzer is substantially equivalent to the legally marketed bilirubin assay on the Roche Hitachi Analyzers (K981632), the Radiometer ABL735 (K991417), the Beckman LX®20 System (K011213) and the Kodak Vitros System (K840880).

4) Device Description

The Roche Diagnostics OMNI S Analyzer is a fully automated critical care analyzer intended to be used for the measurement of pH, PO2, PCO2, sodium, potassium, ionized calcium, chloride, hematocrit, glucose, lactate, urea/BUN, bilirubin, total hemoglobin, oxygen saturation, oxyhemoglobin, deoxyhemoglobin, carboxyhemoglobin and methemoglobin in samples of whole blood, serum, plasma and aqueous solutions as appropriate.

5) Intended use

The OMNI S bilirubin claim is for the determination of neonatal bilirubin in newborns using whole blood samples.

6) Substantial equivalence – Similarities and Differences

The bilirubin parameter for use on the OMNI S Analyzer was compared to several legally marketed analyzers in the method comparison studies. It was compared to the bilirubin assay on the Roche Hitachi Analyzers (K981632), the Radiometer ABL735 (K991417), the Beckman LX®20 System (K011213) and the Kodak Vitros System (K840880).

The OMNI S bilirubin claim is for the determination of neonatal bilirubin in newborns using whole blood samples. The primary predicate device is the Radiometer ABL735, which determines neonate bilirubin using the same sample type (whole blood).

The method comparison studies also showed acceptable performance versus other analyzers, the Roche Hitachi Analyzers (K981632), the Beckman LX®20 System (K011213), and the Kodak Vitros System (K840880), which claim the determination of bilirubin in serum and plasma.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAY 1 4 2004

Ms. Jennifer Tribbett
Regulatory Affairs Principal
Roche Diagnostics Corp.
9115 Hague Road
Indianapolis, IN 46256

Re: k040174
Trade/Device Name: Bilirubin Assay on the OMNI S Analyzer
Regulation Number: 21 CFR 862.1113
Regulation Name: Bilirubin (total and unbound) in the neonate test system
Regulatory Class: Class I
Product Code: MQM
Dated: April 5, 2004
Received: April 7, 2004

Dear Ms. Tribbett:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Jean M. Cooper MS, DVM.

Jean M. Cooper, MS, D.V.M.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K040174

Device Name: Bilirubin Assay on the OMNI S Analyzer

Indications For Use:

The Roche Diagnostics OMNI S Analyzer is a fully automated critical care analyzer intended to be used for the measurement of pH, PO2, PCO2, sodium, potassium, ionized calcium, chloride, hematocrit, glucose, lactate, urea/BUN, bilirubin, total hemoglobin, oxygen saturation, oxyhemoglobin, deoxyhemoglobin, carboxyhemoglobin and methemoglobin in samples of whole blood, serum, plasma and aqueous solutions as appropriate.

Prescription Use X AND/OR Over-The-Counter Use ____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Carol C Benson
Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safety

510(k) K040174